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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,525	06/19/2006	Giovanni Mogna	HOFF-39568	7210

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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,525	MOGNA ET AL.	
	Examiner	Art Unit	
	KADE ARIANI	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, and 6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on September 22, 2008, has been received and entered.

New Claims 14 and 15 have been added.

Claims 1, 2, and 6-15 are pending in this application and were examined on their merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/22/2008 has been entered.

Applicant's arguments with respect to claims 1, 2, and 6-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a strain of bacteria belong to the genus *Bifidobacterium*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code

and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 12 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn due to Applicant's amendments to the claims filed on 09/22/2008.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 provides for "a method for preparing a medicament to treat alterations of intestinal microflora", where the claim recites "comprising the steps of providing one or more probiotic bacteria strains.... and using said strain to prepare said medicament", but, since the claim does not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 6, 7, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Alander et al. (in IDS, Letters in Applied Microbiology, 1997, Vol. 24, p.361-364).

Claims 1, 2, 6, and 11are drawn to a process for collecting bacteria adhered to the intestinal wall comprising the steps of carrying out a colonoscopy with brushes adapted for cell collection and collecting probiotic adhered to the intestinal wall, wherein

the collection is carried out in various segments of the bowels by means of individual brushes, the brushes are connected to conventional colonoscopy equipment, the process is characterized in that each strain collected is cultured and analyzed separately, wherein the segments of the intestinal wall consist of the distal ileum, right colon, transverse colon, left colon, and sigma.

Claim 7 is drawn to a process for isolating bacterial strains comprising collecting strains according to claim 1.

Alander et al. disclose a process for collecting bacteria adhered to the intestinal wall of a subject, by colonoscopy through brushes (sampling was done by a brush), collection is carried out in several intestine segments of individual (biopsies from the ascending, transverse and descending colon) (see Abstract, p.362, 1st column 1st and 2nd paragraphs, Colonoscopy & biopsies" and "Sampling & cultivation"). Alander et al. also disclose isolating and identification of probiotic bacteria *L. rhamnosus* GG, cultivation on a selective media, L. GG-like colonies from biopsies were selected and further tested (p.362 2nd column 1st paragraph lines 13-14 and 2ns paragraph lines 5-8).

Alander et al. therefore clearly anticipate the claimed process for collecting bacteria and characterizing the probiotic bacteria.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alander et al. (in IDS, Letters in Applied Microbiology, 1997, Vol. 24, p.361-364) in view of Kaur et al. (European Journal of Pharmaceutical Sciences, Feb. 2002, Vol. 15, p.1-9)

Claims 1 and 8-10 are drawn to a process for collecting bacteria adhered to the intestinal wall, and a method for preparing a medicament to treat alterations of intestinal microflora comprising the steps of providing one or more probiotic bacteria strains obtained by the process of claim 1 and using said strain to prepare said medicament.

As mentioned immediately, above Alander et al. teach a process for collecting bacteria adhered to the intestinal wall.

Alander et al. do not teach a method for preparing a medicament to treat alterations of intestinal microflora, providing one or more probiotic bacteria strains and using said strain to prepare said medicament. However, Kaur et al. teach probiotic compositions/formulations prepared by using probiotic bacterial strains, commercially marketed formulations of probiotics (p.4 Table 1. 1st column). Kaur et al. also teach a method of preparing a composition comprising probiotics (p.7 1st column last paragraph and 2nd column). Kaur et al. further teach improving intestinal microbial balance using probiotic food supplement (Abstract).

It must be noted that although the probiotic bacteria taught by Kaur et al. are not selected by the method of claim 1, however, Claims 8, 9 and 10 are product-by process claims and as indicated in MPEP, [E]ven though a product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Moreover, the process steps recited in claim 1, "a process for collecting bacteria adhered to the intestinal wall comprising the steps of carrying out a colonoscopy with brushes....collecting probiotic adhered to the intestinal wall..." would not be expected to impart distinctive structural characteristics to the probiotic bacterial strain (final product), and does not change the cells of the probiotic bacterial strain. Therefore, the claimed probiotic composition is met by Kaur et al.

Therefore, a person of ordinary skill in the art at the time the invention was made could have been motivated to use the method as taught by Alander et al. with predictable results of collecting probiotic bacteria adhered to the intestine. Moreover, a person of ordinary skill in the art at the time the invention was made would have been motivated to use the probiotic bacteria collected by the method of Alander et al. according to the teachings of Kaur et al. with predictable results of preparing a food composition or probiotic composition comprising the isolated probiotic bacteria.

Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alander et al. (in IDS, Letters in Applied Microbiology, 1997, Vol. 24, p.361-364) in view of Ishibashi et al. (The American Journal of Clinical Nutrition, 2001, Vol. 73 (suppl) p.465S-470S).

As mentioned immediately above, Alander et al. teach a process for collecting bacteria adhered to the intestinal wall.

Alander et al. do not teach the probiotic bacteria belong to the *Bifidobacterium* genus. However, Ishibashi et al. teach the main bacterial strains used in probiotics include lactic acid bacteria and bifidobacteria that inhabit the intestinal tracts of humans and animals (Abstract).

Therefore, a person of ordinary skill in the art at the time the invention was made, would have been motivated to use the method as taught by Alander et al. according to the teachings of Ishibashi et al. with predictable results of collecting probiotic bacteria belong to genus *Bifidobacteria* from the intestinal wall. The motivation as taught by Ishibashi et al. would be because bifidobacteria inhabit the intestinal tracts of human and animals.

Claims 1, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alander et al. (in IDS, Letters in Applied Microbiology, 1997, Vol. 24, p.361-364) in view of Patwari et al. (Indian J Pediatr, 2001, Vol. 68, No.6, p.515-518) and further in view of Cronmiller et al. (Helicobacter, 1999, Vol. 4, No. 3, p.198-203) and further in

view of Reuter, G., (Current Issues in Intestinal Microbiology, 2001, Vol. 2, No. 2, p.43-53).

Claims 1 and 12-14 are drawn to a process for collecting bacteria adhered to the intestinal wall comprising the steps of carrying out a colonoscopy with brushes adapted for cell collection and collecting probiotic adhered to the intestinal wall, wherein the collection is carried out in various segments of the bowels by means of individual brushes, the collection is carried out in various segments of the bowels by means of four individual brushes, wherein a biopsy channel is washed with saline before introducing each of said individual brushes, and wherein the collection is carried out in the distal ileum by means of a first individual brush, and in the right colon by means of a second individual brush, ..., and in the left colon by means of a fourth individual brush.

As mentioned immediately above, Alander et al. teach a process for collecting bacteria adhered to the intestinal wall of a subject, by colonoscopy through brushes, collection is carried out in several intestine segments of individual (biopsies from the ascending, transverse and descending colon) (see Abstract, p.362, 1st column 1st and 2nd paragraphs, "Colonoscopy & biopsies").

Alander et al. do not teach the collection is carried out by means of four individual brushes, wherein a biopsy channel is washed with saline before introducing each of said individual brushes, and wherein the collection is carried out in the distal ileum by means of a first individual brush, and in the right colon by means of a second individual brush, ..., and in the left colon by means of a fourth individual brush. However, Patwari et al. teach endoscopic brush cytology (EBC) is a useful diagnostic tool and care must

be taken to minimize contamination while performing EBC by thoroughly cleaning the brush and the tip to minimize contamination (Abstract, and p.516 Material & Methods).

Moreover, Cronmiller et al. teach transmission of bacteria via contaminated endoscopic device (Abstract). Cronmiller et al. further teach washing and flushing of the suction biopsy channel with physiological saline (p.200 2nd column 3rd paragraph). Thus, a person of ordinary skill in the art at the time the invention was would have known the need to practice aseptic technique and to change the brush and to use different brush in order to collect bacteria from different parts of the intestine to avoid contamination.

Further motivation to use different individual brushes during the collection of the probiotic bacteria is in Reuter who teaches, the gastrointestinal microflora is a very complex community, within the gastrointestinal tract, different habitats have to be recognized, e.g. mouth, stomach small intestine, especially large jejunum and ileum, large intestine and rectum. The balance is influenced primarily by the host's individuality this means interpersonal variation exists (p. 43, Introduction 2nd column 2nd paragraph, and p.49 Table 6.). Reuter further teaches the selection of suitable species or strains as probiotics culture is a very critical step (p.44, 1st column, last paragraph).

Therefore, in view of the above teachings, a person of ordinary skill in the art at the time the invention was made would have been motivated to practice aseptic techniques and to change the brush during the collection of samples from different segments of the intestinal wall in the method as taught by Alander et al. with predictable results of collecting the probiotic bacteria adhered to various segments of the intestinal wall. Applicant is directed to pages 12-13 of KSR v Teleflex (500 US ___ 2007) " ... the

Court has held that a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651